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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,246	12/06/2001	Robert Sixto JR.	SYN-064C	5866
27316 7590 04/30/2008 MAYBACK & HOFFMAN, P.A. 5722 S. FLAMINGO ROAD #232 FORT LAUDERDALE, FL 33330				
EXAMINER				
ERIZO, DARWIN P				
ART UNIT		PAPER NUMBER		
3773				
MAIL DATE		DELIVERY MODE		
04/30/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/010,246

**Applicant(s)**

SIXTO ET AL.

**Examiner**

Darwin P. Erez

**Art Unit**

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 17, 18 and 21-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17, 18 and 21-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

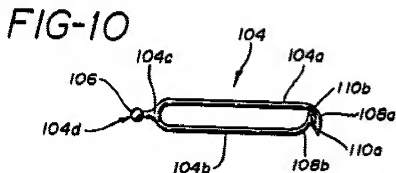
1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 7, 17, 18, 21-25, 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,222,961 to Nakao et al.

Nakao discloses a surgical clip, as shown in the attached Fig. 10 below, which comprises a first arm; a second arm that is substantially parallel to the first arm; and a bridge connecting said first and second arms to form a substantially U-shaped structure. The arms also include a retainer portion attached thereto for penetrating through the tissue (Fig. 4). The length of the retainer, as shown below, is at least 3.14 times the distance between the arms when the arms are substantially parallel. The retainer is also capable of being deformed (change in shape) since the clip is taught as being made of a flexible material (col. 9, lines 41-44). Nakao also discloses the retainer having a tip portion that has a thickness smaller than the thickness of the arm; wherein the retainer is a pair of deformable retainers having tip portions; and wherein a clip applier is provided that is capable holding a plurality of clips (Fig. 23A).



### Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 5, 6, 8-10, 26, 27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. and in further view of US 4,719,917 to Barrows et al., and as evidenced by US 5,002,562 to Oberlander.

Nakao discloses all the limitations of the claims except for the retainer being decouplable from the arms. However, Barrows discloses a similar type of clip/stapling device, wherein the retainer portion of the device is capable of being decoupled from the arms, and wherein the arms have a slot for holding the retainer portion (Fig. 10). This type of arrangement allows for the device to be easily removed from the patient with minimum discomfort (col. 1, lines 60-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Nakao to have decouplable retainers because it would allow the device to be removed from the patient with minimum discomfort. It is noted that Nakao discloses the device to be made of a flexible metallic material while Barrows discloses a bioabsorbable material. However, the use of flexible bioabsorbable material is well known in the surgical clip/staple art, as evidenced by US 5,002,562 to Oberlander in col. 2, lines 11-12. Thus, the device of Nakao would be fully functional with a flexible metallic or with a flexible bioabsorbable material.

### ***Response to Arguments***

5. Applicant's arguments filed 1/14/08 have been fully considered but they are not persuasive.

The applicant's amendment to the independent claims to recite the limitation of the second arm being parallel to the first arm, and a bridge having a substantially static U-shaped structure is not sufficient to overcome the rejections under 35 USC 102 to Nakao or 35 USC 103 to Nakao in view of Barrows and Oberlander. As seen in Fig. 10, which is disclosed above, the clip of Nakao has a state in which the first and second

arms are "substantially parallel". Once the clip is applied, the U-shaped bridge will also have a static U-shaped structure. Therefore, the clip of Nakao has a static state in which the second arm is substantially parallel to the first arm and the bridge is substantially U-shaped.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/  
Primary Examiner, Art Unit 3773